

Remarks

Claims 25-45 are pending in the application. Reconsideration is respectfully requested.

Rejection Under 35 USC § 103

Claims 25-45 were rejected under 35 USC § 103 as being obvious over WO 98/39000 (WO) in view of US Patent No. 5,278,176 to Lin (hereafter "Lin") and Nath et al. or WO in view of Nath et al. This rejection is traversed for the following reasons..

WO 98/39000 describes the compounds of the claimed invention, i.e., donepezil and compounds of Formula (I). However, WO 98/39000 does not disclose or suggest (i) a method for treating substance abuse in a patient in need thereof comprising administering a therapeutically effective amount of donepezil or a pharmaceutically acceptable salt thereof.

Lin does not cure the deficiencies of WO 98/39000 to disclose the presently claimed invention. Lin is directed to compounds that are nicotinic agonists (*see* Lin at Abstract; column 1, lines 5-8; column 6, lines 58-60; column 21, lines 58 to column 22, line 25; column 22, lines 55-62). The invention claimed in the instant application is directed to the use of compounds that are cholinesterase antagonists (i.e., cholinesterase inhibitors). Moreover, Lin's compounds are structurally unrelated to the claimed compounds (i.e., donepezil, compounds of Formula (I)). There is no teaching or suggestion in Lin which would lead one of skill in the art to conclude that the nicotine derivative agonists described therein may be substituted with the cholinesterase antagonists of the instant claims. Lin in combination with WO 98/39000 does not render the claimed invention obvious. Withdrawal of this portion of the rejection is respectfully requested.

The Examiner's rejection based on Nath et al. is not understood, as no arguments or remarks related to Nath et al. have been presented. Furthermore, Applicant's counsel has been unable to locate this reference in the file history. Withdrawal or clarification is requested.

The Examiner has provided comments regarding Kish (abstract only). It appears that the Examiner may believe that Kish et al. can be combined with WO 98/39000 to obtain the presently claimed invention. Applicants respectfully disagree.

According to Kish et al., "mean ChAT levels were normal in all cortical and subcortical brain areas examined" in a group of chronic users of cocaine, methamphetamine and heroin. Kish et al. found aberrant results in 2 of 12 methamphetamine users, suggesting impairment of

"cognitive function requiring a normal nucleus basalis cholinergic neuronal system." The authors suggest that "studies of cognitive and brain cholinergic status in high dose users of MA are warranted," a conclusion that further research is needed. The statements in Kish et al. are speculative and based upon a small cohort of research subjects. Applicants respectfully submit that reduced cholineacetyltransferase activity found occasionally in the brains of methamphetamine users (if even validated by further research) would not suggest to a person of ordinary skill in the art the conclusion that cholinesterase inhibitors be administered for the treatment of substance abuse. It is particularly noted that cholinesterase inhibitors are not mentioned in the cited abstract.

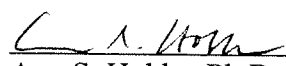
Because neither Lin nor Kish et al. cure the deficiencies of WO 98/39000 to disclose or suggest the presently claimed invention, Applicants respectfully request that the rejection under 35 USC § 103 be withdrawn.

Conclusion

An early and favorable reconsideration and allowance of claims 25-45 is respectfully requested. The Examiner is encouraged to contact the undersigned to expedite prosecution of this application.

Respectfully submitted,

Date: 11/17/08


Ann S. Hobbs, Ph.D.
Registration No. 36,830
VENABLE LLP
575 7th Street, NW
Washington, DC 20004
Phone: 202-344-4614